

PCT #5  
JC10 Rec'd PCT/PTO 09 NOV 2005

Docket No.: 4705-0111PUS1  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Mirian HAYASHI et al.

Application No.: 10/538,071 ✓

Confirmation No.: ---

Filed: June 9, 2005

Art Unit: N/A

For: PROCESS FOR THE DETERMINATION OF  
THE PRIMARY STRUCTURE OF THE  
MESSENGER RNA CODING FOR THE  
HUMAN RECOMBINANT  
ENDOOLIGOPEPTIDASE A (HEOPA)  
[AF217798]...

Examiner: Not Yet Assigned

**INFORMATION DISCLOSURE STATEMENT**  
**(SUBMISSION AFTER FILING OF AN APPLICATION BUT BEFORE FINAL**  
**REJECTION OR NOTICE OF ALLOWANCE OR CONCURRENTLY WITH A RULE**  
**1.114 RCE APPLICATION)**

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, applicant(s) hereby submit(s) an Information Disclosure Statement for consideration by the Examiner.

I. LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION

The patents, publications, or other information submitted for consideration by the Office are listed on the PTO-SB08(s), attached hereto.

II. COPIES

☒ a. Copies of cited U.S. patents and patent application publications are not included.  
Copies of foreign patent documents and non-patent literature are included.

☐ b. Some or all of the documents listed on the PTO-SB08 are not enclosed because they were cited in the International Search Report and copies should already be in the PTO file. If copies are needed, please contact the undersigned.

☐ c. REFERENCES PREVIOUSLY CITED OR SUBMITTED - Pursuant to 37 C.F.R. §1.98(d), consideration of information listed on the PTO-SB08 form(s) is requested since any patents, publications, or other information which are listed on the PTO-SB08 form(s) but for which copies are not enclosed herewith, were previously cited by or submitted to the PTO in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. § 120:

U.S. Appl. No(s) and U.S. Filing Date

### III. CONCISE EXPLANATION OF THE RELEVANCE

(check at least one box)

☒ a. DOCUMENTS IN THE ENGLISH LANGUAGE - The patents, publications, or other information listed on the attached PTO SB08 are in the English language and therefore, do not require a statement of relevancy.

☐ b. DOCUMENTS NOT IN THE ENGLISH LANGUAGE - A concise explanation of the relevance of all patents, publications, or other information listed that is not in the English language is as follows:

☐ c. ENGLISH LANGUAGE SEARCH REPORT - An English language version of the search report or action that indicates the degree of relevance found by the foreign office is attached, thereby satisfying the requirement for a concise explanation. See MPEP 609(III)(A)(3).

☐ d. OTHER - The following additional information is provided for the Examiner's consideration.

IV. FEES (check one box)

☐ a. This Information Disclosure Statement is being filed concurrently with the filing of a new patent application; therefore, no fee is required.

☐ b. This Information Disclosure Statement is being filed concurrent with the filing of a continuation-in-part, continuation, or divisional patent application; therefore, no fee is required.

☐ c. This Information Disclosure Statement is being filed within three months of the filing date of a national application (37 C.F.R. § 1.97(b)(1)). No fee or statement is required.  
(This section is not to be used with RCE's.)

☐ d. This Information Disclosure Statement is being filed within three months of the date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. § 1.97(b)(2)). No fee or statement is required.

☐ e. This Information Disclosure Statement is being filed concurrently with the filing of a Request for Continued Examination under § 1.114 (37 C.F.R. § 1.97(b)(4)). No fee or statement is required.

☒ f. This Information Disclosure Statement is being filed before the mailing date of a first Action on the merits (37 C.F.R. § 1.97(b)(3)). No fee or statement is required. In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the statement under 37 C.F.R. § 1.97(e) below, or, if no statement has been made, charge our deposit account for the fee as required by 37 C.F.R. § 1.17(p).

☐ g. This Information Disclosure Statement is being filed before the mailing date of a Final Office Action under 37 C.F.R. § 1.113 (See 37 C.F.R. § 1.97(c)(1)) or before the mailing date of a Notice of Allowance under 37 C.F.R. § 1.311 (See 37 C.F.R. § 1.97(c)(2)).

☐ No statement; therefore, a fee as required by 37 C.F.R. § 1.17(p) is attached.  
or

☐ See the statement below. No fee is required.

V. STATEMENT UNDER 37 C.F.R. § 1.97(e)

(check only one box)

The undersigned hereby states that:

☐ a. **Each item of information contained in the IDS was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than 30 days prior to the filing of this IDS; or**

☐ b. Each item of information contained in the IDS was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS; or

☐ c. No item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of the IDS.

☐ d. Some of the items of information were cited in a communication from a foreign Patent Office. As to this information, the undersigned states that each item of information contained in the IDS was first cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby states that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application and, to the best of my knowledge after making reasonable

inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

VI. PAYMENT OF FEES (check one box)

☐ The required fee is listed on the attached Fee Transmittal.


☒ No fee is required.

If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule and charge the appropriate fee to Deposit Account No. 02-2448.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Dated: November 9, 2005

Respectfully submitted,

By   
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Attachment(s):

☒ PTO-SB08  
☒ Documents

Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/538,071
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				First Named Inventor	Mirian HAYASHI
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	1	of	3	Attorney Docket Number	4705-0111PUS1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	CA	NOMURA et al., "Isolation of human cDNA clones of myb-related genes, A-myb and B-myb", Nucleic Acids Research, Vol. 16, No. 23, 1988, pp.11075-11089	
	CB	JULIANO et al., "A Selective Assay For Endooligopeptidase A Based On The Cleavage of Fluorogenic Substrate Structurally Related to Enkephalin", Biochemical and Biophysical Research Communications, Vol. 173, No. 2, (1990), pp.647-652	
	CC	KITAWAGA et al., "An F-box protein, FWD1, mediates ubiquitin-independent proteolysis of $\beta$ -catenin", The EMBO Journal, Vol. 18, No. 9, (1999), pp.2401-2410	
	CD	ROGISTER et al., "Review From Neural Stem Cells to Myelinating Oligodendrocytes", Molecular and Cellular Neuroscience, Vol. 14, (1999), pp. 287-300	
	CE	SIDOW et al., "A novel member of the F-box MVD40 gene family, encoding dactylin, is disrupted in the mouse dactylaplasia mutant", Nature Genetics, Vol. 23, (1999), pp. 104-107	
	CF	WESTON, "Myb proteins in life, death and differentiation", Current Opinion in Genetics & Development, (1998), pp.76-81	
	CG	SWEENEY et al., "Nude-L, a novel Lis1-interacting protein, belongs to a family of vertebrate coiled-coil proteins", Mechanisms of Development, Vol. 101, (2001), pp.21-33	
	CH	SWEENEY et al., "Lissencephaly associated mutations suggest a requirement for the PAFAH1B heterotrimeric complex in brain development", Mechanisms of Development, Vol. 92, (2000), pp.263-271	
	CI	OZEKI et al., "Disrupted-in-Schizophrenia-1 (DISC-1): Mutant truncation prevents binding to Nudel-like (NUDEL) and inhibits neurite outgrowth", PNAS, Vol. 100, No. 1, (2003), pp. 289-294	
	CJ	NIETHAMMER et al., "NUDEL is a Novel Cdk5 Substrate that Associates with LIS1 and Cytoplasmic Dynein", Neuron, Vol. 28, (2000), pp.697-711	
	CK	SASAKI et al., "A LIS1/NUDEL/Cytoplasmic Dynein Heavy Chain Complex in the Developing and Adult Nervous System", Neuron, Vol. 28, (2000), pp.681-696	
	CL	HAYASHI et al., "Expression of endo-oligopeptidase A in the rat central nervous system: a non-radioactive in situ hybridization study", Molecular Brain Research, Vol. 89, (2001), pp.86-	

Examiner Signature	Date Considered
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Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>			<b>Complete if Known</b>		
			Application Number	10/538,071	
			Filing Date	June 9, 2005	
			First Named Inventor	Mirian HAYASHI	
			Art Unit	N/A	
			Examiner Name	Not Yet Assigned	
Sheet	2	of	3	Attorney Docket Number	4705-0111PUS1

		93	
CM	SHRIMPSON et al., "Development and characterization of novel potent and stable inhibitors of endopeptidase EC 3.4.24.15" Biochem. J., Vol. 345, (2000), pp.351-356		
CN	CAMARGO et al., "Susceptibility of a Peptide Derived from Bradykinin to Hydrolysis by Brain Endo-oligopeptidases and Pancreatic Proteinases", The Journal of Biological Chemistry, Vol. 254, No. 12, (1979), pp.5304-5307		
CO	CAMARGO et al., "Structural requirements of bioactive peptides for the interaction with endopeptidase 22.19", Peptide Chemistry, (1993), pp. 205-208		
CP	CAMARGO et al., "Structural features that make oligopeptidases susceptible substrates for hydrolysis by recombinant thimet oligopeptidase", Biochem. J., Vol. 324, (1997), pp. 517-522		
CQ	CAMARGO et al., "Involvement of Endo-Oligopeptidases A and B in the Degradation of Neurotensin by Rabbit Brain", Journal of Neurochemistry, Vol. 42, No. 6, (1984), pp.1758-1761		
CR	JACCHIERI et al., "A comparative conformational analysis of thimet oligopeptidase (EC 3.4.24.15) substrates", Journal of Peptide Research, Vol. 51, (1998), pp.452-459		
CS	OLIVERIA et al., "Isolation of Brain Endopeptidases: Influence of Size and Sequence of Substrates Structurally Related to Bradykinin", Biochemistry, Vol. 15, No. 9, (1976), 1967-1974		
CT	PORTARO et al., "Free ATP inhibits thimet oligopeptidase (EC 3.4.24.15) activity, induces autophosphorylation <i>in vitro</i> , and controls oligopeptide degradation in macrophage", Eur. J. Biochem., Vol. 268, (2001), pp.1-9		
CU	MEDERIOS et al., "Distribution and properties of endo-oligopeptidases A and B in the human neuroendocrine system", Journal of Endocrinology, Vol.135, (1992), pp. 579-588		
CV	Oliveria et al., "Substrate Specificity Characterization of Recombinant Metallo Oligo-Peptidases Thimet Oligopeptidases and Neurolysin", Biochemistry, Vol. 40, (2001), pp. 4417-4425		
CW	HAYASHI et al., "Species Specificity of Thimet Oligopeptidase (EC 3.4.24.15)", Biol. Chem., Vol. 377, (1996), pp.283-291		
CX	JONES-VILLENEUVE et al., "Retinoic Acid Induces Embryonal Carcinoma Cells to Differentiate into Neurons and Glial Cells", The Journal of Cell Biology, Vol. 94, (1982), pp.253-262		
CY	JIRACEKI et al., "Development of Highly Potent and Selective Phosphinic Peptide Inhibitors of Zinc Endopeptidase 24-15 Using Combinatorial Chemistry", Journal of Biological Chemistry, Vol. 270, No. 37, (1995), pp.21701-21706		
CZ	TAYLOR et al., "Evolutionary constraints on the Disrupted in Schizophrenia locus", Genomics, Vol. 81, (2003), pp.67-77		
CA1	OLIVERIA et al., "Localization of Endo-Oligopeptidase (EC 3.4.22.19) in the Rat Nervous Tissue", J. Neurochem., Vol. 55, No. 4, (1990), 1114-1121		
CB1	SILVA et al., "Thimet Oligopeptidase (EC 3.4.24.15), a Novel Protein on the Route of MHC Class I Antigen Presentation", Biochemical and Biophysical Research Communications, Vol. 255, (1999), pp.591-595		
CC1	FERRO et al., "Endo-Oligopeptidase A, a Putative Enkephalin-Generating Enzyme, in the Vertebrate Retina", Journal of Neurochemistry, Vol. 57, No. 5, (1991), pp.1643-1649		
CD1	KITAGAWA et al., "Direct association of LISI, the lissencephaly gene product, with a mammalian homologue of a fungal nuclear distribution protein, rNUDE", FEBS Letters, Vol. 479, (2000), pp.57-62		
CE1	HUH et al., "Functional Requirement for Class I MHC in CNS Development and Plasticity", Science, Vol. 290, (2000), pp.2155-2159		
CF1	HAYASHI et al., "Molecular and Immunochemical Evidences Demonstrate That Endooligopeptidase A is the Predominant Cytosolic Oligopeptidase of Rabbit Brain", Biochemical and Biophysical Research Communications, Vol. 269, (2000), pp. 7-13		
CG1	GOMES et al., "Dynorphin-Derived Peptides Reveal the Presence of a Critical Cysteine for the		

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Sheet	3	of	3	Attorney Docket Number	4705-0111PUS1

		Activity of Brain Endo-oligopeptidase A", Biochemical and Biophysical Research Communications, Vol. 197, No.2 , (1993), pp.501-507	
	CH1	FERRO et al., "Secretion of a Neuropeptide-Metabolizing Enzyme Similar to Endopeptidase 22.19", Biochemical and Biophysical Research Communications, Vol. 191, No. 1, (1993), pp. 275-281	
	CI1	PORTARO et al., "Thimet Oligopeptidase and the Stability of MHC Class I Epitopes in Macrophage Cytosol", Biochemical and Biophysical Research Communications, Vol. 255, (1999), pp. 596-601	

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<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

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